

Application No.: 10/553,643

Docket No.: SAIME 3.3-003

IN THE DRAWINGS

Attachment: Replacement Sheets

REMARKSSpecification

In response to the Examiner's remarks, Applicant is submitting a new abstract. The term "consisting of" has been deleted from line 1, and the current abstract contains 148 words.

Information Disclosure Statement

In response to the Examiner's remarks, an information disclosure statement compliant with 37 CFR 1.98(a)(2) and containing all references cited therein, is being submitted concurrently with this response.

Drawings

In response to the Examiner's objections, the originally filed drawings have been replaced with new drawings, which comply with 37 CFR 1.84(p)(4) and 37 CFR 1.121(d). Accordingly, the specification has been amended to reflect any changes in the drawings. Applicant notes that only the reference characters and units were amended in the drawings. No substantive changes were made.

Claim rejections under 35 U.S.C. § 112 First Paragraph

The Examiner rejected claim 10 for lack of enablement based on the grounds that the language "disabling means" lacks enablement because one of ordinary skill in the art would not be able to make the device without further disclosure. In response to the Examiner's rejection, claim 10 has been amended to read "is configured to be disabled." Support for this amendment can be found in the specification at paragraphs 35, 60, 214, 216, and 243. Withdrawal of the rejections and entry of the foregoing amendments is respectfully requested.

Claim rejections under 35 U.S.C. § 112 Second Paragraph

The Examiner rejected claims 1, 4, 9, 14, and 21 based on the use of the words "elaborate" and "elaborating." The Examiner stated that the claimed limitations could not be properly ascertained based on the ordinary definition in the art. In claim 1, the word "elaborate" has been replaced with the term "compute the pressure setting." In all other instances, the words "elaborate" and "elaborating" have been deleted from the rejected claims and replaced with the language "computes" or "computing." Support for these amendments can be found for example, in the specification at paragraph 91.

The Examiner rejected claims 1, 6-11, and 22 based on the use of the language "associated to." The Examiner stated that it was unclear whether the recited structure or limitation following the term "associated to" was positively being claimed.

In claim 1, the word "associated" has been changed to "connected." This change positively shows that the turbine of claim 1 is connected to the speed sensor of claim 1. Support for this amendment can be found in the specification at paragraphs 11, 34, 55 and 58.

In claims 6, 7, 8, 9, and 11, the phrase "wherein said means of calculation is associated to," has been replaced with the phrase "further comprising." Claim 10 has been amended to replace the phrase "is associated to disabling means" with the phrase "is configured to be disabled."

Claim 22 has been amended to replace the phrase "associated with a stopping," with the phrase, "disabled." Support for the addition of the term "disabled" can be found in the specification at paragraphs 11, 35, 60, 214, 216 and 243.

Claims 6-8, 12, 18-20 and 24 were rejected by the Examiner on the grounds that the structure performing the

invention was unclear. Based on the Examiner's rejection, all of these rejected claims have been amended to include the limitation "stored in a memory." Support for the term "memory" can be found in the specification at paragraphs 11, 218 and 224.

Claims 8, 20, 10 and 16 have been amended overcome the lack of antecedent basis.

Applicant has amended all of the claims rejected under 35 U.S.C. § 112 and where indicated, provided support in the specification. Withdrawal of the rejections and entry of the foregoing amendments is respectfully requested.

Claim rejections under 35 U.S.C. § 101

The Examiner rejected claims 1-14 under 35 U.S.C. 101 based on the grounds that the language "to carry the pressurized gas to a patient" "appears to be claiming the human body in functional language." (*Office Action*, p.5) Applicant has adopted the suggestion of the Examiner and amended claim 1 to include the phrase "adapted to carry the pressurized gas to a patient." Withdrawal of the rejections and entry of the foregoing amendments is respectfully requested.

Claim rejections under 35 U.S.C. § 102

Claim 1 has been amended to emphasize that the means of calculations "compute the pressure setting using only" the "speed signal" of a rotating element of the turbine. Furthermore, claim 1 is combined with former claim 5, to emphasize that the "detection of new inspiratory or expiratory cycles" by the means of calculation is also made "using only said speed signal." A similar amendment was made to independent claim 15, which is combined with former claim 17.

The Examiner cites *Brydon* (Unites States Patent No. 5,740,795) as a document relevant for the patentability of claim 1. *Brydon* is already acknowledged in the patent

application (cf. [0157], EP 0656216 being the European patent application equivalent of United States Patent No. 5,740,795).

Brydon is concerned with the estimation of flow and detection of breathing in a CPAP apparatus. *Brydon* states that modifications of the airflow which are due to the respiration of the patient will alter parameters such as the turbine motor's speed and/or current.

Brydon further explains that it proposes to use specific signals to detect the points at which the patient starts to inhale and exhale. As exposed at col. 3 l.8-10 (cf. *Brydon* United States Patent No. 5,740,795), these specific signals can be derived either from the motor speed and power measurements (first option), or from the spill valve position and power measurements (second option).

In the first option, motor speed is thus used in some way for detecting the beginning/end of respiratory cycles. However, it has to be noted that motor speed is in no way used by itself, as a single parameter, to detect the respiratory cycles. This parameter is indeed systematically used in combination with power measurements or current measurements.

This is understandable, since turbines known at the priority date of *Brydon* had quite a significant inertia-in the order of at least 1500 g.cm². For such turbines, a change in the airflow conditions would not change turbine speed before some inertia time. Thus, in order to detect such airflow changes in "real time" (or at least as fast as possible, which is of course desired), the mere monitoring and exploitation of turbine speed could not be appropriate.

Brydon uses as a main parameter not turbine speed but motor power, in order to detect airflow changes as fast as possible. This parameter will indeed vary faster than the

turbine speed, which can change only after some time because of the turbine inertia. This is not the case for the claimed invention, since turbine speed in itself requires no filtering, and can be exploited *per se*.

Indeed, in the embodiment of Figure 1a, an output signal representative of the motor current is used (cf. col.3, lines 39-46) to detect expiratory cycles through an inhalation/exhalation detector. Similarly, in the embodiment of Figure 1b, a measure of the time instantaneous power consumed by the motor is used to detect expiratory cycles.

Therefore, a significant difference between *Brydon* and claim 1 is linked to the fact that in the case of the claimed invention the control of the turbine and the detection of the respiratory cycles are made on the basis of turbine speed only.

It should be further noted that the systematic exploitation of motor power in the case of *Brydon* makes it necessary to filter the signals based on power (cf. e.g. low-pass circuit filter 28 and high-pass filter 30).

This is not the case for the claimed invention, since turbine speed in itself requires no filtering, and can be exploited *per se*.

Furthermore, the invention allows a "real time" control possible, by contrast to *Brydon* in which the control is performed on the basis of flow (cf. col. 3 ll.33-36) with the drawback that an important time is needed for a modification in the turbine operation conditions to translate into a modification of flow. Withdrawal of the rejections and entry of the amendments is respectfully requested.

Claim rejections under 35 U.S.C. § 103

Claims 8-9, 15-21 and 23-24 are rejected under 35 U.S.C. 103(a) as being obvious over *Brydon*. Based on the

foregoing discussion, in combination with the present claim amendments, it would not have been obvious to one of skill in the art to practice the claimed invention. Accordingly, withdrawal of the rejections and reconsideration of claims 8-9, 15-21 and 23-24 is respectfully requested.

Claims 10, 12 and 22 are rejected under 35 U.S.C. 103(a) as being obvious over *Brydon* in view of *Rapoport et al.* Applicant respectfully submits that for the reasons stated above, *Brydon* does not teach all of the claimed elements as argued by the Examiner. Additionally, *Rapoport* does not teach the remaining elements of the claims 10, 12 and 22.

Rapoport describes an apparatus and method for detecting obstructive apnea and controlling the continuous positive airway pressure (CPAP) applied to a patient. *Rapoport* describes two embodiments for this apparatus.

In the embodiment of Figure 9, a flow sensor measures the flow rate in a tube 21 carrying air from a flow generator 22 to a patient. A signal generator processes this measurement in order to detect flow limitation. In response to this detection, the signal generator controls the flow generator and thus the CPAP in the tube (cf. col.5, lines 49-65).

In the embodiment of Figure 18, a pressure sensor 90 is used together with a flow sensor 72 in order to measure the pressure and flow rate in a tube linking a blower to the patient. Using these measurements, a microprocessor controls the blower and thus the pressure in the tube (cf. e.g. col. 3, lines 19-43)).

In *Rapoport*, the control of the flow generator and the detection of the respiratory cycles are never carried out using only the speed signal measurement of a turbine rotating element. Thus, the man skilled in the art could not cure the

deficiencies of *Brydon* using the teaching of *Rapoport* in order to arrive to the subject matter of claims 1 and 15. Accordingly, withdrawal of the rejections and reconsideration of claims 1 and 15 is respectfully requested.

Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over *Brydon* in view of *Farrugia et al.* Applicant respectfully submits that, for the reasons stated above, *Brydon* does not teach all of the claimed elements as asserted by the Examiner. Additionally, *Farrugia* does not teach the remaining elements of claims 2 and 14.

Farrugia describes an apparatus and method for flow estimation during CPAP treatment of a patient. In *Farrugia*, the pressure of the gas flowing from a turbine is measured at a known operational speed and compared to an estimation of the pressure of gas that would be delivered at this rotational speed if there was no flow. The difference between the measured pressure and the estimated pressure provides an estimation of the gas flow (cf. Figure 3).

Thus, *Farrugia* does not teach nor suggest the control of a turbine and the detection of respiratory cycles using only the speed signal measurement of said turbine.

One of ordinary skill in the art could not cure the deficiencies of *Brydon* with the teaching of *Farrugia* in order to arrive to the subject matter of claims 2 and 14. Accordingly, withdrawal of the rejections and reconsideration of claims 2 and 14 is respectfully requested.

As already demonstrated above, *Brydon* does not control the turbine operation and the detection of the respiratory cycles by using only the turbine rotation speed signal, but uses instead the motor current and power signals.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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